

DOCKET NO.: TJU-2115
PATENT APPLICATION

SERIAL NO.: 08/789,270
FILED: JANUARY 28, 1997

The specification has been amended to include the required reference to government support and cross reference to related applications. No new matter has been added.

The claims have been amended to more clearly define the invention.

Claim 14 has been amended to recite that the instructions provided in the kit include instructions for steps for performing a method and for analyzing the data generated by performance of the method using reagents in the kit. The specification contains an adequate written description of the subject matter of claim 14 as amended. Support for the amendment is found throughout the specification such as on page 14, line 28 to page 22, line 9, and in particular, page 21, line 32 to page 22, line 9. No new matter has been added.

Claim 19 has been amended to recite that the instructions provided in the kit include instructions for steps for performing a method and for analyzing the data generated by performance of the method using reagents in the kit. The specification contains an adequate written description of the subject matter of claim 19 as amended. Support for the amendment is found throughout the specification such as on page 25, line 28 to page 28, line 37, and in particular, page 28, lines 28-32. No new matter has been added.

Provided herewith are copies of Form 1449 from parent

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application Serial Number 08/305,056.

Provided herewith are copies of In re Miller, 164 U.S.P.Q. 46 (C.C.P.A. 1969), and In re Gulack, 217 U.S.P.Q. 401 (C.A.F.C. 1983) which are relevant legal precedent provided for the Examiner's consideration.

Claims 9-19 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 5,601,990.

Applicant provides herewith a Terminal Disclaimer pursuant to 37 C.F.R. 1.321 to obviate the rejection under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 5,601,990 as applied to claims 9-19. Claims 9-19 are in condition for allowance.

Claim 19 has been rejected under 35 U.S.C. 103 as being unpatentable over Garbers et al. (PN 5,237,051). Garbers et al. discloses amplification of rat ST receptor from mRNA and primers for performing the same. Garbers et al. does not disclose kits.

It is asserted that it would be obvious to assemble the reagents used by Garbers et al. It is asserted that instructions are conventional and that the preamble in Applicant's claim is a statement of intended use that does not impart patentability.

Claim 19 has been amended to more clearly define the inventions, specifically the description of the instructions

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provided in the kit. As amended, the instructions are defined as reciting steps for performing the assay and analyzing the data. In particular, claim 19 as amended recites that the instructions include directions for analyzing data. According to the instructions, assay results that show that the individual's sample contains mRNA that encodes ST receptors indicates that the individual has metastasized colorectal cancer.

This element clearly distinguishes the present invention over Garbers et al. which neither teaches nor suggests the analysis of data step provided in the instructions in the present invention. This element of the instructions is not a statement of intended use but rather a functional element of the claim.

Although the element is printed matter, it does not render the claim unpatentable. The invention as a whole is patentable over the prior art. The combination of the instructions with the reagents for performing the assay is neither taught nor suggested by the prior art.

The invention as defined by claim 19 as amended is patentable over Garbers et al. Applicant respectfully requests that the rejection of claim 19 as unpatentable over Garbers et al. be withdrawn.

Claims 14-18 has been rejected under 35 U.S.C. 103 as being unpatentable over Vaandrager et al. (J. Biol. Chem.

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268(3):2174-2179, January 25, 1993). Vaandrager et al. discloses immunodetection of ST receptors on cells using antibodies raised to the carboxy terminal of the protein. Vaandrager et al. does not disclose kits.

It is asserted that it would be obvious to assemble the reagents used by Vaandrager et al. It is asserted that instructions are conventional and that the preamble in Applicant's claim is a statement of intended use that does not impart patentability.

Claim 14 has been amended to more clearly define the inventions, specifically the description of the instructions provided in the kit. As amended, the instructions are defined as reciting steps for performing the assay and analyzing the data. In particular, claim 14 as amended sets forth that instructions include directions for analyzing data in which assay results which indicate that the individual's sample contains ST receptors which indicates that the individual has metastasized colorectal cancer.

This element clearly distinguishes the present invention over Vaandrager et al. which neither teaches nor suggests the analysis of data step provided in the instructions in the present invention. This element of the instructions is not a statement of intended use but rather a functional element of the claim.

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Although the element is printed matter, it does not render the claim unpatentable. The invention as a whole is patentable over the prior art. The combination of the instructions with the reagents for performing the assay is neither taught nor suggested by the prior art.

The invention as defined by claim 19 as amended is patentable over Vaandrager et al. Applicant respectfully requests that the rejection of claim 19 as unpatentable over Vaandrager et al. be withdrawn.

For the foregoing reason, Applicants respectfully urge that claims 9-19 are in condition for allowance. Applicant respectfully requests that claims 9-19 be allowed at this time. A Notice of Allowance is earnestly solicited.

Respectfully submitted,



Mark DeLuca
Registration No. 33,229

Date: Sept 11, 1997
WOODCOCK WASHBURN KURTZ
MACKIEWICZ & NORRIS
One Liberty Place - 46th Floor
Philadelphia, PA 19103
(215) 568-3100

Attachments: Terminal Disclaimer to Obviate a Double Patenting
Rejection Over a Prior Patent
Copies of Form 1449 from Serial Number 08/305,056
In re Miller, 164 U.S.P.Q. 46 (C.C.P.A. 1969)
In re Gulack, 217 U.S.P.Q. 401 (C.A.F.C. 1983)